

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

_____)	
UNITED STATES OF AMERICA)	
)	
Plaintiff,)	CRIMINAL NO. 14 CR10363
)	
v.)	
)	
BARRY CADDEN <i>et al.</i>)	
)	
Defendants.)	
_____)	

REMAINING DEFENDANTS' REQUEST FOR JURY INSTRUCTIONS

Pursuant to Fed. R. Crim. P. 30 and this Court's Scheduling Order, defendants Gene Svirskiy, Christopher Leary, Joseph Matthew Evanosky, Sharon Carter, Alla Stepanets, Gregory Conigliaro, Kathy Chin, and Michelle Thomas (the "remaining defendants") hereby request that the Court give the attached jury instructions in this case. The preliminary instructions are based on and largely the same as those requested in the Barry Cadden trial. The final instructions are based on and are largely the same as those given in the Barry Cadden and Glenn Chin trials, except as otherwise noted, and when modifications are dictated by differences in defendants' job titles and charges. Remaining defendants have endeavored to highlight their additions to the substantive final legal instructions in yellow for the Court's convenience. Remaining defendants also seek a mail fraud instruction as part of the explanation of the RICO predicate acts, as opposed to waiting until the mail fraud counts, and have largely used the Court's previous mail fraud language in that proposed section.

The remaining defendants reserve the right to supplement, modify, or withdraw these requested instructions in light of any additional requests filed by the government, the Court's rulings during trial, and the evidence ultimately admitted at trial.

Respectfully submitted,

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Dated: September 18, 2018

CERTIFICATE OF SERVICE

I, Dana M. McSherry, hereby certify that this document was filed on September 18, 2018, via the ECF system, and was sent electronically on that date to the parties' counsel of record.

/s/ Dana M. McSherry

Dana M. McSherry

DEFENDANTS' REQUESTED PRELIMINARY JURY INSTRUCTIONS

DEFENDANTS' REQUESTED PRELIMINARY INSTRUCTION 1

Duties of the Jury¹

Ladies and gentlemen: You are now the jury in this case, and I want to take a few minutes to tell you something about your duties as jurors and to give you some instructions. At the end of the trial I will give you more detailed instructions. Those instructions will control your deliberations.

It will be your duty to decide from the evidence what the facts are. You, and you alone, are the judges of the facts. You will hear the evidence, decide what the facts are, and then apply those facts to the law I give to you. That is how you will reach your verdict. In doing so you must follow that law whether you agree with it or not. The evidence will consist of the testimony of witnesses, documents and other things received into evidence as exhibits, and any facts on which the lawyers agree or which I instruct you to accept.

You should not take anything I may say or do during the trial as indicating what I think of the believability or significance of the evidence or what your verdict should be.

¹ First Circuit Pattern Jury Instruction § 1.01 (Criminal 2016 ed.)

DEFENDANTS' REQUESTED PRELIMINARY INSTRUCTION 2

Nature of Charges²

This criminal case has been brought by the United States government. I will sometimes refer to the government as the prosecution. The government is represented at this trial by two Assistant United States Attorneys: Amanda Strachan and George Varghese.

There are eight defendants in this trial: Gene Svirskiy, Christopher Leary, Joseph Matthew Evanosky, Sharon Carter, Alla Stepanets, Gregory Conigliaro, Kathy Chin, and Michelle Thomas. Mr. Svirskiy is represented by Jeremy Sternberg and Christopher Iaquinto. Mr. Leary is represented by Paul Kelly and Sarah Walsh. Mr. Evanosky is represented by Mark Pearlstein, Dana McSherry and Jennifer Aronoff. Ms. Carter is represented by Michael Pineault. Ms. Stepanets is represented by Jack Cunha, Helen Holcomb and Charles Hope. Mr. Conigliaro is represented by Dan Rabinovitz and Shawn Lu. Ms. Chin is represented by Joan Griffin. Ms. Thomas is represented by Michael Bourbeau.

These eight individuals have been accused by the government of various and differing violations of federal law. Mr. Svirskiy, Mr. Leary, and Mr. Evanosky are charged with violations of the Racketeer Influenced and Corrupt Organizations Act, also known as "RICO." Mr. Svirskiy, Mr. Leary, Mr. Evanosky, Ms. Carter and Ms. Stepanets are charged with conspiracy to violate the RICO statute. Ms. Carter, Ms. Stepanets and Mr. Conigliaro are charged with a separate conspiracy to defraud the United States. Mr. Svirskiy, Mr. Leary, and Mr. Evanosky are charged with mail fraud. Mr. Svirskiy, Mr. Leary, Mr. Evanosky, Ms. Stepanets, Ms. Chin and Ms. Thomas are charged with various violations of the Federal Food, Drug and Cosmetic Act. I will summarize these allegations for you in a moment.

² Adapted from First Circuit Pattern Jury Instruction § 1.02 (Criminal 2016 ed.).

Although the Defendants are being tried together, the charges against each of them differ, and you will have to give separate consideration to the case against each Defendant. Do not think of the Defendants as a group. You must separately consider the evidence against each Defendant on each offense charged, and you must return a separate verdict for each Defendant on each offense.³

Each defendant has pled not guilty to all of these charges and denies committing the crimes charged. Each defendant is presumed innocent, and you may not find him or her guilty unless all of you unanimously find that the government has proven his or her guilt beyond a reasonable doubt.

³ The last sentence is from Third Circuit Pattern Jury Instructions 1.16 (Separate Consideration – Multiple Defendants Charged with the Same Offenses) (fourth sentence); *see also* 1 L. Sand, *Modern Federal Jury Instructions (Crim.)*, Instr. 3-8 (2009).

DEFENDANTS' REQUESTED PRELIMINARY INSTRUCTION 3

The Government as a Party⁴

You are to perform the duty of finding the facts without bias or prejudice as to any party, with complete fairness and impartiality.

The fact that the prosecution is being brought in the name of the United States of America entitles the government to no greater consideration than that accorded to any other party to a case. By that same token, it is entitled to no less consideration. All parties, whether government or individuals, stand as equals at the bar of justice.

⁴ Adapted from 1 L. Sand et al., *Modern Federal Jury Instructions (Crim.)*, Instr. 2-5 (2010). The second paragraph of the Sand instruction ("The case is important to the government for the enforcement of criminal laws is a matter of prime concern to the community. Equally, it is important to the defendant, who is charged with serious crime[s].") is omitted as unnecessary and slanted in favor of the government.

DEFENDANTS' REQUESTED PRELIMINARY INSTRUCTION 4

Presumption of Innocence and Burden of Proof

There are some important rules that govern criminal trials.

The first rule is that each defendant is presumed innocent unless and until his or her guilt is proven beyond a reasonable doubt, and this presumption alone is sufficient to acquit him. The charges brought by the United States here are accusations, and only that; they are not proof of anything at all. A defendant is innocent in the eyes of the law, unless and until you, the jury, decide, by a unanimous vote, that the government has proved his guilt beyond a reasonable doubt.⁵

That brings me to the second rule. In a criminal case, the burden of proving guilt is on the government. It has that burden throughout the trial. A defendant never has the burden of proving his innocence. The right of a defendant to put the government to its burden of proof is one of the most fundamental guarantees of our Constitution. This means that a defendant has no obligation to produce evidence or to call witnesses in order to be found not guilty, nor can he be required to testify. The burden rests on the government and the government alone to prove each and every element of the crimes charged beyond a reasonable doubt, and a defendant has a right to rely upon the failure or inability of the government to meet its burden in establishing any essential element of the crimes with which he or she is charged.⁶

⁵ Adapted from the Court's model final jury instruction on Presumption of Innocence.

⁶ Adapted from the Court's model final jury instruction on Burden of Proof.

DEFENDANTS' REQUESTED PRELIMINARY INSTRUCTION 5

Preliminary Statement of Elements of Crime⁷

In order to help you follow the evidence, I will now give you a brief summary of the crimes charged, each of which the government must prove beyond a reasonable doubt as to each defendant so charged.

Count 1 alleges that Mr. Svirskiy, Mr. Leary, and Mr. Evanosky violated the Racketeer Influenced and Corrupt Organizations Act, commonly referred to as "RICO." This is a law that Congress passed in 1970 seeking to eradicate organized crime in the United States. Before you deliberate at the end of this case I will give you more detailed instructions concerning the elements the government must prove beyond a reasonable doubt to convict any of them of violating RICO, and of all of the other crimes it alleges in each Count. But for starters, to prove a RICO violation, the government must establish the following five things:

First: That an enterprise existed as alleged in the Indictment;

Second: That the enterprise affected interstate or foreign commerce;

Third: That the defendant was associated with or employed by the enterprise;

Fourth: That the defendant engaged in a pattern of racketeering activity, which consisted of the knowing commission of at least two racketeering "predicate acts"—that is, two individual but related criminal acts within a ten-year period; and

Fifth: That the defendant conducted or participated in the conduct of the enterprise through that pattern of racketeering activity.

Mr. Svirskiy, Mr. Leary, and Mr. Evanosky are accused of committing RICO predicate acts of mail fraud. These acts are also charged as standalone crimes, which I will explain to you

⁷ Adapted from First Circuit Pattern Jury Instruction § 1.04 (Criminal 2016 ed.).

soon. Good faith is a complete defense to the charged racketeering acts and mail fraud. If a defendant acts in good faith, he cannot be guilty of the crime of mail fraud.

Count 2 alleges that Mr. Svirskiy, Mr. Leary, Mr. Evanosky, Ms. Carter, and Ms. Stepanets conspired to violate the RICO statute. To convict any defendant of this Count, the government must prove beyond a reasonable doubt: First, that an agreement existed between two or more persons to conduct or participate in the affairs of a racketeering enterprise; second, that the agreement included an agreement to commit at least two predicate acts of federal mail fraud in violation of the RICO statute; and, third, that the defendant in question was a knowing and willful participant in the agreement, in the sense that he knew the nature, scope and criminal purpose of the agreement and joined it with every intent to see it succeed in its unlawful goals. As I will further instruct you at the end of this case, good faith is a complete defense to the crime of conspiracy.

Count 3 alleges that Ms. Carter, Ms. Stepanets and Mr. Conigliaro conspired to defraud the United States by impeding the ability of the Food and Drug Administration (FDA) to perform its regulatory functions. To convict any defendant of this Count, the government must prove beyond a reasonable doubt, first, that an agreement existed between two or more persons to impair, obstruct, or defeat the ability of the FDA to perform its lawful functions; second, that the defendant in question was a knowing and willful participant in that agreement (in the same sense I just explained); and third, that at least one of the alleged conspirators took an overt act in furtherance of the conspiracy, that is, an affirmative step towards the accomplishment of the illegal goals of the agreement. As with Count 2, good faith is a complete defense to the crime of conspiracy charged in Count 3.

Counts 32, 42, and 47–56 allege that Mr. Svirskiy committed mail fraud. **Counts 33, 39–43, and 46** allege that Mr. Leary committed mail fraud. **Counts 34, 35, 37, and 41** allege that Mr. Evanosky committed mail fraud. To convict a defendant of these Counts, the government must prove beyond a reasonable doubt that he knowingly and willfully participated in a scheme to defraud NECC's customers by making material misrepresentations or concealing material facts, and used the United States mail to execute this scheme. As I will instruct you again at the end of this case, as with conspiracy, if a defendant acts in good faith, he cannot be guilty of the crime of mail fraud.

Count 85 alleges that Mr. Svirskiy distributed adulterated drugs, in violation of the federal Food, Drug and Cosmetic Act. **Count 86** alleges the same against Mr. Leary, and **Counts 87 and 88** allege the same against Mr. Evanosky. To convict a defendant of these counts, the government must prove beyond a reasonable doubt that the defendant, acting with the intent to defraud or mislead, caused drugs to be delivered into interstate commerce that he knew were adulterated in that he prepared, packed or held the drugs under insanitary conditions such that the defendant had a reasonable expectation they could become contaminated. As with conspiracy and mail fraud, the government must prove beyond a reasonable doubt that Mr. Svirskiy, Mr. Leary and Mr. Evanosky did not act in good faith.

Count 91 alleges that Mr. Svirskiy distributed misbranded drugs whose labeling was false and misleading, in violation of the federal Food, Drug and Cosmetic Act. **Counts 92 and 94** allege that Mr. Leary distributed misbranded drugs whose labeling was false and misleading, in violation of the federal Food, Drug and Cosmetic Act. To convict a defendant of these Counts, the government must prove beyond a reasonable doubt that he acted with the intent to defraud or mislead and caused drugs to be delivered into interstate commerce that were misbranded,

meaning that their labels contained a materially false or misleading representation. Again, good faith is a complete defense to this charge.

Counts 96–98, 101–03 and 108 allege that Ms. Stepanets dispensed misbranded drugs—that is, without a written prescription, in violation of the federal Food, Drug and Cosmetic Act. **Counts 104–107** allege the same against Ms. Chin. **Counts 108 and 109** allege the same against Ms. Thomas. To convict on these Counts, the government must prove beyond a reasonable doubt that a defendant, acting with the intent to defraud or mislead, introduced drugs into interstate commerce for which a prescription was required, and that the drugs were dispensed to end-user patients without such a prescription. Again, good faith is a complete defense.

What I have just given you is only a preliminary outline of the Counts charged. At the end of the trial I will give you a final instruction on these matters in more detail. If there is any difference between what I just told you, and what I tell you in the instructions I give you at the end of the trial, the instructions given at the end of the trial govern.

DEFENDANTS' REQUESTED PRELIMINARY INSTRUCTION 6

Caution – Allegations Regarding the United States Pharmacopeia⁸

As I just mentioned, I will give you full instructions on the criminal charges at the end of this trial. Before you begin hearing the evidence, however, I am going to instruct you on one aspect of the case that relates to the government's allegations.

You will hear testimony about the United States Pharmacopeia, also known as the USP. The USP contains recommended industry guidelines that are formulated, amended, and published by the United States Pharmacopeia Convention, a private, nonprofit organization. Although the name of the organization contains the words "United States," the standards contained in the USP are not drafted or approved by the United States government.

The USP is not a criminal law. It is not passed by Congress. It does not define crimes or their elements. Please keep in mind throughout the trial that a departure from the USP's recommended guidelines—even if intentional—is not itself a criminal offense. In this case, this means that if you determine that any conduct by a defendant departed from one or more of the USP's guidelines, that would not by itself establish that he or she committed any of the crimes for which he or she is charged.

⁸ Adapted from the language in Court's Memorandum and Order on Motion to Dismiss Counts 1-2 & 4-94 of Indictment Based on Use of Private Industry Code (Dkt. #573); see also *United States v. Mix*, No. CRIM.A. 12171, 2014 WL 2625034, at *6-7 (E.D. La. June 12, 2014) (instructing jury that violation of internal company policy, even an intention violation, is not itself a criminal offense); *United States v. Singhal*, 876 F. Supp. 2d 82, 103 (D.D.C. 2012); *United States v. Ramos*, 537 F.3d 439, 459-60 (5th Cir. 2008).

DEFENDANTS' REQUESTED PRELIMINARY INSTRUCTION 7

Evidence; Objections; Rulings; Bench Conferences⁹

I have mentioned the word “evidence.” Evidence includes the testimony of witnesses, both from direct examination and from cross-examination, documents and other things received as exhibits (such as testimony by senior members of the FDA before Congress), and any facts that have been stipulated—that is, formally agreed to by the parties.

There are rules of evidence that control what can be received into evidence. Lawyers for both sides have an absolute right and an obligation to object when they believe something is being offered into evidence that it is not permitted by the rules of evidence. You should not hold an objection against any of the lawyers or the party they represent.

When a lawyer does object to a piece of evidence, I will rule on the admissibility of that evidence. However, my ruling as to whether the piece of evidence is or is not admissible does not indicate any opinion about the weight or effect of such evidence.

⁹ Adapted from First Circuit Pattern Jury Instruction § 1.05 (Criminal 2016 ed.).

DEFENDANTS' REQUESTED PRELIMINARY INSTRUCTION 8

Credibility of Witnesses¹⁰

In deciding what the facts are, you may have to decide what testimony you believe and what testimony you do not believe. You may believe everything a witness says or only part of it or none of it.

In deciding what to believe, you may consider a number of factors, including the following: (1) the witness's ability to see or hear or know the things the witness testifies to; (2) the quality of the witness's memory; (3) the witness's manner while testifying; (4) whether the witness has an interest in the outcome of the case or any motive, bias or prejudice; (5) whether the witness's testimony is contradicted by anything the witness said or wrote before trial or by other evidence; and (6) how reasonable the witness's testimony is when considered in the light of other evidence which you believe. In determining the credibility of a witness, you may also consider whether the witness was granted immunity by the government, or if the witness had any other agreement with the government that might affect his/her credibility.

¹⁰ Adapted from First Circuit Pattern Jury Instruction § 1.06 (Criminal 2016 ed.).

DEFENDANTS' REQUESTED PRELIMINARY INSTRUCTION 9

Cooperating and/or Immunized Witnesses¹¹

You may hear evidence in this case from witnesses who have cooperation agreements with the government and/or will testify under a grant of immunity from the government.

“Immunity” means that the witness’ testimony may not be used against her in any subsequent criminal proceeding.

Some people who are cooperating witnesses or witnesses with immunity are entirely truthful when they testify. Still, you should consider the testimony of these cooperators or immunized witnesses with particular caution. They may have reason to make up stories or exaggerate what others did because he or she wants to help him or herself.

¹¹¹ Adapted from First Circuit Pattern Instruction 2.08: Caution as to Cooperating Witness/Immunized Witness (2018).

DEFENDANTS' REQUESTED PRELIMINARY INSTRUCTION 10

Government Employee as Witness¹²

You will hear testimony from some witnesses who are employed by the federal or state governments. The fact that a witness is employed by the government does not entitle the witness's testimony to more weight or credibility than that of any other witness's testimony. In addition, in assessing the credibility of a witness who is employed by the government, you may consider whether the witness has a personal or professional interest in the outcome of the case.

¹² This instruction is based on the Fifth Circuit's decision in *United States v. Gallardo-Trapero*, 185 F.3d 307, 320 (5th Cir. 1999) (improper for prosecutor to state in closing argument that employees of the government wouldn't lie), and the Seventh Circuit's decision in *United States v. Martin*, 507 F.2d 428 (7th Cir. 1974) ("[I]t was particularly important for the defendant to know of any prejudices the jurors may have had about the Government or about the credibility of government agents."). The First Circuit has held that appeals to "believe the police or FBI because of their history, integrity, or public service is inappropriate." *United States v. Torres-Galindo*, 206 F.3d 136, 142 (1st Cir. 2000). This instruction merely protects against jurors' reasonable inclination to reach this conclusion with or without express invitation.

DEFENDANTS' REQUESTED PRELIMINARY INSTRUCTION 11

Conduct of the Jury

To insure fairness, you as jurors must obey the following rules:

First, do not talk among yourselves about this case, or about anyone involved with it, until the end of the case when you go to the jury room to decide on your verdict.

Second, do not talk with anyone else about this case, or about anyone who has anything to do with it, until the trial has ended and you have been discharged as jurors. Do not discuss the case with anyone else in person, in writing, by phone or by any electronic means, such as text messaging, email, Facebook, Snapchat, LinkedIn, Twitter, blogging, any internet chat room, or any other social media.¹³ “Anyone else” includes members of your family and your friends. You may tell them that you are a juror, but do not tell them anything about the case until after you have been discharged by me.

Third, do not let anyone talk to you about the case or about anyone who has anything to do with it. If someone should try to talk to you about the case or about anyone who is involved with the case, please report it to me immediately.

Fourth, during the trial do not talk with or speak to any of the parties, lawyers, or witnesses involved in the case—you should not even pass the time of day or talk about the weather with any of them. It is important not only that you do justice in this case, but that you also give the appearance of doing justice. If a person from one side of the case sees you talking to a person from the other side—even if it is simply to pass the time of day—an unwarranted and unnecessary suspicion about your fairness might be aroused. If any lawyer, party, or witness

¹³ This sentence, dealing with social media, is adapted from 1 L. Sand et al., *Modern Federal Jury Instructions (Crim.)*, Instr. 2-21 (Contact with Others) (second sentence).

does not speak to you when you pass in the hall, ride the elevator or the like, it is because they are not supposed to talk or visit with you.

Fifth, do not read any news stories, online coverage, or articles about the case or about anyone involved with it, or listen to any radio or television reports about the case or about anyone involved with it.

Sixth, do not do any research on the internet about anything in the case or consult blogs or dictionaries or other reference materials, and do not make any investigation about the case on your own.

Seventh, do not discuss the case or anyone involved with it, or your status as a juror, on any social media or look up information on the internet about any of the defendants, lawyers, witnesses or other participants in this trial.

Eighth, if you need to communicate with me simply give a signed note to the courtroom security officer to give to me.

Ninth, do not make up your mind about what the verdict should be until after you have gone to the jury room to decide the case and you and your fellow jurors have discussed the evidence. It is critical to the fairness of this trial that you keep an open mind until you have heard all the evidence.¹⁴

¹⁴ Adapted from First Circuit Pattern Jury Instruction § 1.07 (Criminal 2016 ed.). Defendants' alterations of the pattern instructions are de minimis.

DEFENDANTS' REQUESTED PRELIMINARY INSTRUCTION 12

Outline of Trial¹⁵

The first step in the trial will be the opening statements of each side. These opening statements will tell you what each side believes the evidence will show.

Next, the government will offer the evidence that it says will prove all of the elements of the charges against the defendants beyond a reasonable doubt. The defendants' lawyers will also put on part of their defense through the cross-examination of the witnesses the government calls.

After the government rests, the defendants' lawyers may present further evidence on their behalf, but are not required to do so. I remind you that each defendant is presumed innocent, and the government must prove the guilt of each defendant beyond a reasonable doubt. The defendants do not have to prove their innocence.

After you have heard all the evidence on both sides, the government and the defense will each be given time for their final arguments.

You will also be given detailed instructions about the rules of law before you begin deliberating. Your deliberations will be secret. You will never have to explain your verdict to anyone.

¹⁵ Adapted from First Circuit Pattern Jury Instruction § 1.09 (Criminal 2016 ed.).

DEFENDANTS' REQUESTED FINAL JURY INSTRUCTIONS

DEFENDANTS' REQUESTED JURY INSTRUCTION 1

Presumption of Innocence; Burden of Proof; Proof beyond a Reasonable Doubt

The Court has a model instruction on these topics, which the remaining defendants have not reproduced here.

DEFENDANTS' REQUESTED JURY INSTRUCTION 2

Jury to Consider Only the Defendants Before It, and Each Defendant Individually

You are about to be asked to decide whether the government has proven each of the eight Defendants in this case guilty beyond a reasonable doubt. You are not being asked whether any other person has been proven guilty. Your verdict should be based solely upon the evidence or lack of evidence as to each of the eight Defendants as individuals, in accordance with my instructions and without regard to whether the guilt of other people has or has not been proven.

Although the Defendants are being tried together, the charges against each of them differ. You must consider each charge and each Defendant's involvement in that charge separately, and you must return a separate verdict on each Defendant for each crime with which he is charged.

Do not think of the Defendants as a group. The question of guilt is personal and individual. Your verdict of guilty or not guilty must be based solely upon the evidence about each Defendant. The case against each Defendant, on each charge, stands or falls upon the proof or lack of proof against that Defendant alone, and your verdict as to any Defendant on any charge should not control your decision as to any other Defendant or any other charge.¹⁶

¹⁶ This instruction was not given at the Cadden and Glenn Chin trials, but Defendants urge its adoption here in light of the large number of defendants in this trial. It is adapted from 1 L. Sand et al., *Modern Federal Jury Instructions (Crim.)*, Instr. 2-18 (2010) and Third Circuit Pattern Jury Instructions 1.16 (Separate Consideration – Multiple Defendants Charged with the Same Offenses) (fourth sentence); see also 1 L. Sand, *Modern Federal Jury Instructions (Crim.)*, Instr. 3-8 (2009); *United States v. Ofray-Campos*, 534 F.3d 1, 22–23 (1st Cir. 2008); *Kotteakos v. United States*, 328 U.S. 750, 772 (1946); *United States v. Wihbey*, 75 F.3d 761 (1st Cir. 1996).

DEFENDANTS' REQUESTED JURY INSTRUCTION 3

Job Title or Corporate Position

You may not find any of the Defendants guilty of any offense simply because of his or her job title or position at NECC. Defendants cannot be held criminally responsible for the acts of others simply by virtue of their position. Your verdict as to each Defendant must be based only on the acts in which that Defendant was personally involved.

DEFENDANTS' REQUESTED JURY INSTRUCTION 4

Evidence at Trial

The Court has a Model Instruction on this topic, which the remaining defendants have not reproduced here.

DEFENDANTS' REQUESTED JURY INSTRUCTION 5

Leading questions

It is permissible for attorneys to use leading questions, that is, questions that suggest their own answer, when cross-examining an opposing or hostile witness. Leading questions can be a useful means of testing the credibility of a witness's statements, but you should be careful to separate the witness's answers from any assertions of fact a leading question might have contained.

DEFENDANTS' REQUESTED JURY INSTRUCTION 6

No Outside Information

Anything you may have seen or heard outside the courtroom during the course of the trial is not evidence. This includes any publicity that preceded your empanelment as jurors and any news or social media accounts of the trial that you may have accidentally encountered during the past [*duration of trial*]. You must decide the case solely on the evidence that was offered and received in open court.

DEFENDANTS' REQUESTED JURY INSTRUCTION 7

Summary Charts

Complex evidence may be presented during a trial in the form of charts and summaries. These charts and summaries are admitted in order to save time and to simplify the inspection of the large number of documents they typically distill. It is, however, the underlying evidence, and the weight that you attribute to it, that gives the charts and summaries their evidentiary value. If you are not satisfied that they accurately reflect the underlying evidence, you are free to reject them.

DEFENDANTS' REQUESTED JURY INSTRUCTION 8

Witness Credibility

The Court has a Model Instruction on this topic, which remaining defendants have not reproduced here.

DEFENDANTS' REQUESTED JURY INSTRUCTION 9

Complicitous Witnesses

The Court has a Model Instruction on this topic, which remaining defendants have not reproduced here. Defendants request that the Court reference Robert Ronzio and Scott Connolly in connection with this instruction, assuming both testify.

DEFENDANTS' REQUESTED JURY INSTRUCTION 10

Government Employees and Law Enforcement Officers as Witnesses

Many of the witnesses who testified are government employees or law enforcement officers. These witnesses are entitled to no more or less credibility than any other witness by virtue of their employment.

DEFENDANTS' REQUESTED JURY INSTRUCTION 11

Expert Witnesses

The Court has a Model Instruction on this topic, which the remaining defendants have not reproduced here. Defendants additionally request that the Court add this sentence to the end of the second paragraph of its model instruction, following “you may disregard the opinion entirely”: “The determination of the facts in this case rests solely with you.”

DEFENDANTS' REQUESTED JURY INSTRUCTION 12

Immunity of Government Witnesses¹⁷

You also heard testimony from several witnesses, including [*names*], who testified under a grant of immunity from prosecution. A witness testifying under a grant of immunity may, of course, be completely truthful, which is why the government is permitted to present the testimony of witnesses who have been promised by the government that their testimony will not be used against them in a criminal prosecution. Still, you should consider the testimony of a witness testifying under a grant of immunity with great care and caution. You should scrutinize the testimony carefully to be certain that it is not shaded or shaped in such a way as to serve the personal interests of the witness or the witness's perception of the government's expectations rather than the interests of truth.

¹⁷ This instruction was given only in the Glenn Chin trial. Defendants request that when giving this instruction, the Court reference the name of any government witness with immunity who testifies in this case, including but not limited to Annette Robinson, Cory Fletcher, and Beth Reynolds.

DEFENDANTS' REQUESTED JURY INSTRUCTION 13

The Indictment

The Court has a Model Instruction on this topic, which the remaining defendants have not reproduced here. With respect to the charges in this case, Defendants request the following instructions:

Mr. Svirskiy has been charged with 16 separate counts of violations of federal law. Mr. Leary has been charged with 11 separate counts. Mr. Evanosky has been charged with eight separate counts. Ms. Carter has been charged with two separate counts. Ms. Stepanets has been charged with nine separate counts. Mr. Conigliaro has been charged with one count. Ms. Chin has been charged with four counts. And Ms. Thomas has been charged with two counts. The numbers of these charges are not in sequence, but that is not a mistake; it is intentional, to fit what the government actually presented at trial.

Mr. Svirskiy, Mr. Leary, and Mr. Evanosky are charged in Count 1 of the Indictment with violating the Racketeer Influenced and Corrupt Organizations Act, more commonly known as "RICO" based on its acronym. The Indictment alleges that Mr. Svirskiy committed 12 predicate acts of federal mail fraud, Mr. Leary committed six predicate acts of federal mail fraud, and Mr. Evanosky committed four predicate acts of federal mail fraud. "Predicate acts" are findings a jury must make in considering whether a RICO violation has occurred. They are not separate counts of an Indictment unless charged as such. That is the case here: The predicate acts each of these three defendants has alleged to have committed are also charged as separate, standalone mail fraud counts, which I will explain to you later.

Count 2 alleges that Mr. Svirskiy, Mr. Leary, Mr. Evanosky, Ms. Carter, and Ms. Stepanets conspired—that is, entered into an agreement with others—to violate the RICO statute. Under federal law, a conspiracy is a separate and distinct crime.

Count 3 charges Ms. Carter, Ms. Stepanets, and Mr. Conigliaro with conspiring with others to defraud the United States by impeding the ability of the Food and Drug Administration, or FDA, to perform its regulatory functions.

Counts 32–35, 37, 39–42, and 47–56 charge the 22 combined RICO predicate acts of mail fraud as separate substantive crimes.

Counts 85–88 charge Mr. Svirskiy, Mr. Leary, and Mr. Evanosky with violations of the Food, Drug and Cosmetic Act, for allegedly introducing drugs into interstate commerce that had been prepared in unsanitary conditions. Mr. Svirskiy is charged in Count 85, Mr. Leary is charged in Count 86, and Mr. Evanosky is charged in counts 87 and 88. These charges are in connection with some of the same acts at issue in the RICO predicate acts and standalone mail fraud counts. Counts 91–92 charge Mr. Svirskiy with introducing drugs into interstate commerce that bore false or misleading labels; Count 94 charges Mr. Leary with the same.

Finally, Counts 96–98 and 101–109 charge Ms. Stepanets, Ms. Chin, and Ms. Thomas with dispensing drugs into interstate commerce without valid prescriptions. Ms. Stepanets is charged in Counts 96–98, 101–103, and 108; Ms. Chin is charged in counts 104–107, and Ms. Thomas is charged in Counts 109 and 109.

DEFENDANTS' REQUESTED JURY INSTRUCTION 14

General Instruction Regarding Theories of Defense and Burden

In response to the allegations of the Indictment, the Defendants state that they did not commit any crime. They have also raised several specific defenses. I will describe some of these to you now, but you must keep in mind that the Defendants have no burden to prove their defenses, and it is the government's burden to prove each and every element of the crimes charged beyond a reasonable doubt. By explaining some of these defenses the Defendants cannot be held to have assumed that burden.

DEFENDANTS' REQUESTED JURY INSTRUCTION 15

Individual Defendants' Specific Instructions Regarding Defenses

[Defendants request leave to submit their Theory of Defense instructions at the close of the evidence.]

DEFENDANTS' REQUESTED JURY INSTRUCTION 16

The USP

You have heard testimony about the United States Pharmacopeia, or USP. These guidelines are formulated and published by a council of experts chosen by the United States Pharmacopeia Convention, a nonprofit organization that owns the copyright to the USP compendium of drug information. The USPC was founded in 1820 by doctors who, as declared in their founding statement, “recognized an essential need for a national lexicon of drug names and formulas in the United States.” The Convention is composed of volunteer members. A Board of Trustees oversees the staff of employees and volunteers who assemble and publish the USP and related materials. Pharmacy Compounding Chapter 797 of the USP, on which the Indictment heavily draws, was promulgated by the USPC in its official version in 2004 and revised in 2008. It is important to remember that the guidelines contained in the USP are not drafted by the United States government. However, when Congress enacted the Food, Drug and Cosmetic Act, it referenced the USP as a source for designing desirable practices for the drug compounding industry. While the USP guidelines may be considered by you in determining the standard of care that the defendants may or may not have exercised, a deviation from a provision of the USP, by itself, is not a criminal violation. Congress did not enact the Pharmacopeia as a criminal statute.

DEFENDANTS' REQUESTED JURY INSTRUCTION 16

COUNT 1: RICO

Nature of Offense Charged

Count 1 charges Mr. Svirskiy, Mr. Leary, and Mr. Evanosky with a violation of the RICO Statute. Specifically, the Indictment alleges that NECC and its affiliate Medical Sales Management, or MSM, were a criminal enterprise through which Mr. Svirskiy, Leary, and Evanosky conducted a pattern of racketeering activity to obtain money and property by fraudulent pretenses.

DEFENDANTS' REQUESTED JURY INSTRUCTION 16

COUNT 1: RICO

Basic Elements of Offense Charged

The RICO statute, section 1962(c) of Title 18 of the United States Code, provides in pertinent part that:

“It shall be unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect interstate or foreign commerce, to conduct or participate directly or indirectly, in the conduct of such enterprise’s affairs through a pattern of racketeering activity.”

To prove that a defendant violated section 1962(c), the government must establish beyond a reasonable doubt each of the following five things:

- First: That an enterprise existed as alleged in the Indictment;
- Second: That the enterprise affected interstate or foreign commerce;
- Third: That the defendant was associated with or employed by the enterprise;
- Fourth: That the defendant engaged in a pattern of racketeering activity, which consisted of the knowing commission of at least two racketeering or predicate acts in a ten-year time period; and
- Fifth: That the defendant conducted or participated in the conduct of the enterprise through that pattern of racketeering activity.

I will now briefly address each of these elements.

DEFENDANTS' REQUESTED JURY INSTRUCTION 17

COUNT 1: RICO

First Element: Enterprise

The first element that the government must prove beyond a reasonable doubt is that an “enterprise” existed. An enterprise must have a structure, common purpose, ongoing existence during the alleged period of criminal activity, and personnel who manage and carry out its affairs. Here, the government has charged that NECC and MSM functioned in combination as an “enterprise” within the meaning of the RICO statute.

DEFENDANTS' REQUESTED JURY INSTRUCTION 18

COUNT 1: RICO

Second Element: Effect on Interstate or Foreign Commerce

The second element the government must prove beyond a reasonable doubt is that the enterprise was engaged in or had an effect upon interstate or foreign commerce. Interstate commerce includes the movement of goods, services, money, or individuals between or among states.

DEFENDANTS' REQUESTED JURY INSTRUCTION 19

COUNT 1: RICO

Third Element: Associated with or Employed by the Enterprise

The third element the government must prove beyond a reasonable doubt is that Mr. Svirskiy, Mr. Leary, and Mr. Evanosky were associated with or employed by the enterprise.

DEFENDANTS' REQUESTED JURY INSTRUCTION 20

COUNT 1: RICO

Fourth Element: Engaged in a Pattern of Racketeering Activity

The fourth element the government must prove beyond a reasonable doubt is that Mr. Svirskiy, Mr. Leary, and Mr. Evanosky engaged in a pattern of racketeering activity. To show a pattern of racketeering activity as to each of the defendants charged with RICO, the government must prove **beyond a reasonable doubt** that each defendant committed at least two racketeering “predicate acts” within ten years of each other. **A “predicate act” is a specific illegal act.** These acts must be related, **not disconnected**, and **must** pose a threat of continuing criminal activity. The government has alleged that Mr. Svirskiy committed 12 such predicate acts of mail fraud, Mr. Leary committed six predicate acts of mail fraud, and Mr. Evanosky committed four predicate acts of mail fraud. I will describe the elements of **mail fraud** in detail.

The concept of relatedness is rooted in the common-sense understanding that disconnected acts do not constitute a pattern, nor are they likely to pose a threat of continued racketeering activity. To prove relatedness, the government must prove that the acts had the same or similar purposes, results, participants, victims, or methods of commission, and are not merely isolated events. To prove a threat of continued racketeering activity, the government must establish that the related racketeering acts extended over a substantial period of time, or that they included a specific threat of repetition extending indefinitely into the future. **A substantial period of time will normally be measured in years, rather than a few weeks or months.**¹⁸ **As with every element, it is the government’s burden to convince you beyond a reasonable doubt that the time period was substantial.**

¹⁸ *Efron v. Embassy Suites (Puerto Rico) Inc., et al.*, 233 F.3d 12, 17-18 (1st Cir. 2000).

DEFENDANTS' REQUESTED JURY INSTRUCTION 21

COUNT 1: RICO

Fifth Element: Conducted or Participated in the Conduct of the Enterprise

The fifth and final element that the government must prove beyond a reasonable doubt is that Mr. Svirskiy, Mr. Leary, and Mr. Evanosky each conducted or participated in the conduct of the enterprise through the pattern of racketeering activity. To prove participation in the conduct of the enterprise, the government must show that Mr. Svirskiy, Mr. Leary, and Mr. Evanosky each played a substantive part in the operation or management of the enterprise and that there is a meaningful connection between each man's illegal acts and the affairs of the enterprise. To show a meaningful connection, the government must establish either that the defendants' position in the enterprise facilitated commission of those illegal acts and that the racketeering acts had some impact or effect on the enterprise; or that the acts were in some way related to the affairs of the enterprise; or, third, that Mr. Svirskiy, Mr. Leary, and Mr. Evanosky were able to commit the acts by virtue of their position or involvement in the affairs of the enterprise.

DEFENDANTS' REQUESTED JURY INSTRUCTION 22

COUNT 1: RICO

Racketeering Acts – Mail Fraud

Count 1 alleges that Mr. Svirskiy committed 12 racketeering predicate acts, which are violations of federal law. These racketeering acts include 12 acts of Mail Fraud in violation of federal law. Count 1 alleges that Mr. Leary committed six racketeering predicate acts—six acts of Mail Fraud in violation of federal law. Count 1 alleges that Mr. Evanosky committed four racketeering predicate acts—four acts of Mail Fraud in violation of federal law. These mail fraud acts are charged both as racketeering predicate acts as part of the Count I RICO offense and as standalone counts in the Indictment. I will explain the elements of a mail fraud violation here and remind you of it again later when I address the standalone mail fraud counts.

The crime of mail fraud is codified at 18 United States Code, section 1341. The statute prohibits the use of the mails or an interstate carrier, public or private, in furtherance of any scheme or artifice to defraud, or to obtain money or property by means of false or fraudulent pretenses, representations, or promises.

Racketeering Acts 54, 64, and 69–78, set out in Count 1, and Counts 32, 42, and 47–56 of the Indictment charge Mr. Svirskiy with violating the federal mail fraud statute directly. Similarly, Racketeering Acts 55, 61–63, 65, and 68, set out in Count 1, and Counts 33, 39–41, 43, and 46 of the Indictment charge Mr. Leary with violating the federal mail fraud statute directly. Racketeering Acts 56–57, 59, and 63, set out in Count 1, and Counts 34–35, 37, and 41 of the Indictment charge Mr. Evanosky with violating the federal mail fraud statute directly.

The Indictment alleges that **beginning in at least 2006 and continuing until in or around October 2012**, these defendants and others devised a scheme to defraud NECC's customers and to obtain

money and property by means of materially false and fraudulent representations regarding the quality and production of NECC's drugs. Specifically, the Indictment alleges that Mr. Svirskiy, Mr. Leary, Mr. Evanosky, and others at NECC failed to properly test NECC's drugs for sterility; failed to wait for test results before shipping NECC's drugs to customers; failed to inform customers about non-sterile and out-of-specification test results of drugs that had been shipped for use in patients; used expired and expiring ingredients in manufacturing NECC's drugs; used expired and expiring stock solutions in manufacturing the drugs; mixed and mislabeled drug lots to conceal the use of expiring older lots or untested newer lots; employed an unlicensed pharmacy technician to manufacture drugs; failed to properly clean and disinfect the clean rooms in which drugs were manufactured; and routinely ignored NECC's internal environmental monitoring reports alerting them to mold and bacteria within the clean rooms.

For you to find Mr. Svirskiy, Mr. Leary, or Mr. Evanosky guilty of committing a predicate act or standalone count of mail fraud, you must be convinced that the government has proven each of the following four things beyond a reasonable doubt:

First: That there was a scheme, substantially as charged in the Indictment, to defraud or to obtain money or property from NECC's customers by means of false or fraudulent pretenses;

Second: That the scheme involved the misrepresentation or concealment of a material fact or matter, or involved a false statement, assertion, half-truth or knowing concealment concerning a material fact or matter;

Third: That Mr. Svirskiy, Mr. Leary, or Mr. Evanosky knowingly and willfully participated in the scheme with the intent to defraud; and,

Fourth: That for the purpose of executing the scheme or in furtherance of the scheme, Mr. Svirskiy, Mr. Leary, or Mr. Evanosky caused a private or commercial interstate carrier, such as Federal Express, to be used on or about the date alleged.

A scheme to defraud is ordinarily accompanied by a desire or purpose to bring about some gain or benefit to oneself or some other person or by a desire or purpose to cause some loss to another. The term “defraud” means to deprive another of something of value by means of deception or cheating. The term “false or fraudulent pretenses” means any false statement or assertion that concerns a material aspect of the matter in question, that was either known to be untrue when made or made with reckless indifference to its truth and made with the intent to defraud. The definition includes actual, direct false statements, as well as half-truths and the knowing concealment of facts. To satisfy its burden of proof that a fact is “material,” the government is not required to show that it succeeded in influencing or deceiving the decision maker to whom it was addressed. Rather, a fact or matter is “material” if it has a natural tendency to influence or is capable of influencing the decision maker involved.

A defendant acts “knowingly” if he is aware of his actions, realizes what he is doing, and does not act out of ignorance, mistake, or accident. Intent or knowledge cannot usually be proved by direct evidence because there is no way to directly scrutinize the workings of the human mind. In determining what Mr. Svirskiy, Mr. Leary, or Mr. Evanosky knew or intended at a particular time, you may consider any statements he made or acts that he did or failed to do in the context of all the other facts and circumstances in evidence.

“Intentionally” means purposefully. “Willfully” means to participate voluntarily with the specific intent to do something that the law forbids. To act with “intent to defraud” means to act willfully and with the specific intent to deceive or cheat for the purpose of either causing some financial loss

to another or to bring about some financial gain to oneself. As with conspiracy, if Mr. Svirskiy, Mr. Leary, and Mr. Evanosky acted in good faith, they cannot be guilty of the crime of mail fraud.

The law regarding mail fraud is written to punish only those who act knowingly and willfully—that is, purposefully to violate the law, and with the specific intent to defraud. The burden of proving fraudulent intent, as with all other elements of a crime, rests with the government. If you find that that a defendant was not a knowing participant in the scheme or that he lacked the specific intent to defraud, you should find him not guilty.¹⁹

It is not necessary for the government to prove that all of the details alleged in the Indictment concerning the scheme or the material transmitted by mail was false or fraudulent or that the use of the mails was intended as the specific or exclusive means of accomplishing the alleged fraud. What must be proven beyond a reasonable doubt is that a defendant knowingly devised or intended to devise a scheme to defraud that was substantially the same as the one alleged in the Indictment, and that the use of the mails, on or about the dates alleged, was closely related to the scheme because a defendant either received something in the mail or caused it to be mailed in an attempt to carry out the scheme. To “cause the mail to be used” is to do an act with knowledge that the use of the mails, including private commercial carriers, will foreseeably follow in the ordinary course of business.

¹⁹ 2 *Modern Federal Jury Instructions (Criminal)*, Instruction 44.01.

DEFENDANTS' REQUESTED JURY INSTRUCTION 23

COUNT 1: RICO

Racketeering Acts – Description of Specific Mail Fraud Acts

The alleged racketeering predicate acts of mail fraud alleged against Mr. Svirskiy, Mr. Leary, and Mr. Evanosky are broken up into three separate groups. The first group, Racketeering Acts 54, 55, 61, 62, and 63, charges that in or around July of 2012 through September of 2012, Mr. Svirskiy, Mr. Leary, Mr. Evanosky, and others knowingly schemed to defraud NECC's customers by shipping to customers throughout the country drugs identified as "sterile" prior to receiving the results of testing confirming the sterility and quality of the drugs. These predicate acts further allege that in furtherance of the same intentional scheme, NECC failed to inform its customers that independent sterility testing had not yet been completed at the time of shipment, and in instances in which Analytical Research Laboratories, or ARL, issued non-sterile or otherwise out-of-specification results, NECC failed to notify the customers of the results, institute a recall, or conduct an investigation into the reason for the results.

The second group, Racketeering Acts 64, 65, and 68, charges that in or around January of 2008 through July of 2012, Mr. Svirskiy, Mr. Leary, and others knowingly schemed to defraud NECC's customers by compounding drugs using an ingredient that had expired on or about January 23, 2007. These predicate acts further allege that in furtherance of the same scheme and to disguise the use of the expired ingredients, Mr. Svirskiy and Mr. Leary completed and caused others to complete documents with fictitious expiration dates. The predicate acts also allege that Mr. Svirskiy, Mr. Leary, and others caused the drugs to be shipped to customers without notifying them of the use of expired ingredients; and, further, that the drugs were labeled with fictitious

beyond-use dates indicating expiration dates three to six months after the date the drugs were made.

The fourth group, Racketeering Acts 69 through 78, charges that from in or around March of 2010 through August of 2012, Mr. Svirskiy and others knowingly represented to customers that NECC complied with Massachusetts pharmacy regulations, even though Scott Connolly, who had voluntarily surrendered his pharmacy technician registration in January of 2009, worked as a pharmacy technician in Clean Room 2, filling cardioplegia orders for hospital customers. These Racketeering Acts also allege that to conceal Mr. Connolly's presence in the clean room from regulators, Connolly logged in using Mr. Cadden's username and password.

With respect to the fourth element of RICO, as set out in Count 1 of the Indictment, the government must prove beyond a reasonable doubt that Mr. Svirskiy committed at least two of the related racketeering predicate acts within ten years of one another, that Mr. Leary committed at least two of the related racketeering predicate acts within ten years of one another, and that Mr. Evanosky committed at least two of the related racketeering acts within ten years of one another. If you reach a unanimous verdict that any of these defendants—Mr. Svirskiy, Mr. Leary, or Mr. Evanosky—is guilty on Count 1, you must then complete the Special Verdict Form attached at the end of the Verdict Slip specifying the predicate acts that you find the government has proved beyond a reasonable doubt. In this regard, you must agree unanimously on the predicate acts for which you find each defendant liable. It is not enough that you collectively believe that a defendant committed two predicate acts. You must agree unanimously on at least two of the same acts. If you cannot come to such an agreement, you must find Mr. Svirskiy, Mr. Leary, and Mr. Evanosky not guilty of Count 1. If you do come to such an agreement on the Special Verdict Form, you will

specify by a check mark those predicate acts which you found proved beyond a reasonable doubt and on which you unanimously relied in reaching a guilty verdict.

DEFENDANTS' REQUESTED JURY INSTRUCTION 24

COUNT 2: RICO Conspiracy

Mr. Svirskiy, Mr. Leary, Mr. Evanosky, Ms. Carter, and Ms. Stepanets are charged in Count 2 with a conspiracy to violate RICO. A “conspiracy” is an agreement between or among two or more persons to accomplish an unlawful purpose, that is, one forbidden by law. Specifically, Count 2 charges that beginning in at least 2006 and continuing until in or around October 2012, Mr. Svirskiy, Mr. Leary, Mr. Evanosky, Ms. Carter, and Ms. Stepanets, along with other individuals, unlawfully and knowingly conspired to violate the RICO statute through a pattern of racketeering activity consisting of multiple acts of mail fraud.

To prove each of these defendants guilty of the crime of RICO conspiracy, the government must prove three essential elements beyond a reasonable doubt.

First: That the agreement to conduct or participate in a criminal racketeering enterprise that is alleged in Count 2 of the Indictment, and not some other agreement or agreements, actually existed at or about the time specified in the Indictment.

Second: That Mr. Svirskiy, Mr. Leary, Mr. Evanosky, Ms. Carter, and Ms. Stepanets knowingly and willfully joined in that agreement with the purpose of seeing it succeed in accomplishing its unlawful goals.

Third: That each defendant knowingly agreed that a conspirator would commit a violation of RICO—that is, commit at least two RICO predicate acts of mail fraud.

A person acts “knowingly” if the act he or she performed was voluntary and intentional, and was not done because of ignorance, mistake, or accident. A person acts “willfully” if he or she acts voluntarily and purposefully with the specific intent to do something the law forbids, that is, with a

bad purpose, either to disobey or disregard the law, and not because of accident, ignorance, good-faith mistake, or some other innocent reason.

With respect to the RICO conspiracy alleged in Count 2, the Indictment alleges and the government must prove:

That Mr. Svirskiy knowingly and willfully entered into an agreement with Barry Cadden, Glenn Chin, Christopher Leary, Joseph Evanosky, Scott Connolly, Sharon Carter, and Alla Stepanets to violate the RICO statute through a pattern of racketeering activity by committing at least two specific predicate acts of mail fraud within a ten-year period.

That Mr. Leary knowingly and willfully entered into an agreement with Barry Cadden, Glenn Chin, Gene Svirskiy, Joseph Evanosky, Scott Connolly, Sharon Carter, and Alla Stepanets to violate the RICO statute through a pattern of racketeering activity by committing at least two specific predicate acts of mail fraud within a ten-year period.

That Mr. Evanosky knowingly and willfully entered into an agreement with Barry Cadden, Glenn Chin, Gene Svirskiy, Christopher Leary, Scott Connolly, Sharon Carter, and Alla Stepanets to violate the RICO statute through a pattern of racketeering activity by committing at least two specific predicate acts of mail fraud within a ten-year period.

That Ms. Carter knowingly and willfully entered into an agreement with Barry Cadden, Glenn Chin, Gene Svirskiy, Christopher Leary, Joseph Evanosky, Scott Connolly, and Alla Stepanets to violate the RICO statute through a pattern of racketeering activity by committing at least two specific predicate acts of mail fraud within a ten-year period.

That Ms. Stepanets knowingly and willfully entered into an agreement with Barry Cadden, Glenn Chin, Christopher Leary, Joseph Evanosky, Scott Connolly, and Sharon Carter to

violate the RICO statute through a pattern of racketeering activity by committing at least two specific predicate acts of mail fraud within a ten-year period.

To prove RICO conspiracy, the government must prove beyond a reasonable doubt that Mr. Svirskiy, Mr. Leary, Mr. Evanosky, Ms. Carter, and Ms. Stepanets knowingly and willfully agreed to become members of this conspiracy, and that they knew of and agreed to the overall criminal purpose of the enterprise. That is, the government must prove that each of these defendants agreed with one or more others to participate in a conspiracy to further the goals of the criminal enterprise.

The government is not required to show that the conspirators entered into an express or formal agreement, or that they directly, by spoken or written words, stated among themselves just what their illegal purpose was, or outlined the details of their scheme or the means by which they hoped to succeed. Indeed, it would be unusual if there was a formal meeting, or a written contract, or even a specific oral agreement. A conspiracy, by its very nature, is a clandestine enterprise. But the government must prove beyond a reasonable doubt that each of these defendants—Mr. Svirskiy, Mr. Leary, Mr. Evanosky, Ms. Carter, and Ms. Stepanets—shared a general understanding of the goals of the conspiratorial agreement. It is not necessary, in order to convict a defendant of a charge of conspiracy, that the objectives or purposes of the conspiracy, whatever they may have been, were achieved or accomplished. The ultimate success or failure of the conspiracy is irrelevant. Rather, the agreement is the essential aspect of the crime of conspiracy.

A person who has no knowledge of or intent to join a conspiracy, but simply acts in a way that furthers some object or purpose of the conspiracy, does not thereby become a conspirator. A

defendant cannot be convicted on the basis of suspicion or surmise. He cannot be convicted because he associated with the wrong people or simply because he knew that they were engaged in

illegal activity, nor can he be convicted because he happened to be present while a crime was being committed by others, even if his actions may appear to have furthered the object of the conspiracy.

Rather, the government must prove beyond a reasonable doubt that a defendant willfully joined the conspiracy and embraced its illegal objectives. Proof that a defendant joined in the agreement must be based on evidence of his own words and actions. You need not find that the defendant knew every detail of the conspiracy, or knew every other co-conspirator, or participated in every conspiratorial act alleged by the government, but the government must prove beyond a reasonable doubt that he was aware of the essential terms of the agreement at issue and intentionally joined the agreement. Even if the defendant was not part of an agreement from its inception, he can be found guilty if at some time during the existence of the conspiracy he knowingly and intentionally became a party to the agreement.

A conspirator cannot be held accountable for the crimes of others that are outside the scope of the agreement to which he is a party or crimes committed by others that he could not have reasonably foreseen. Nor can he be held liable for crimes committed by a co-conspirator prior to his joining the conspiracy, even if he is aware that such crimes took place. But once he joins, and so long as he remains a member of the partnership in crime, he is responsible for the words and actions undertaken by his co-conspirators that are intended to further the conspiracy's goals.

Accordingly, the reasonably foreseeable acts, declarations, statements and omissions of any member of the conspiracy that are in furtherance of the illegal common purpose of the conspiracy, are deemed, under the law, to be the acts of all of the members, and all of the members are responsible for such acts, declarations, statements and omissions. This is so even if such acts were done and statements made in the defendant's absence and without his knowledge.

Since an essential element of the crime of conspiracy is the intent to commit the underlying crime, it follows that good faith on the part of a defendant is a complete defense. If you find that Mr. Svirskiy, Mr. Leary, Mr. Evanosky, Ms. Carter, or Ms. Stepanets believed in good faith that his or her actions were not criminal, even if he was mistaken in that belief, there would be no crime. As with all other material aspects of an offense, these defendants have no burden to establish their good faith. The burden is on the government to prove the lack of good faith beyond a reasonable doubt.

DEFENDANTS' REQUESTED JURY INSTRUCTION 25

COUNT 3: Conspiracy to Defraud the United States

Ms. Carter, Ms. Stepanets, and Mr. Conigliaro are charged in Count 3 with a conspiracy to defraud the United States by impeding the ability of the Food and Drug Administration (FDA) to perform its regulatory functions. A conspiracy is an agreement between or among two or more persons to accomplish an unlawful purpose, that is, one forbidden by law.

To prove defendants guilty of the crime of conspiracy, the government must prove three essential elements beyond a reasonable doubt.

First: That at or about the time alleged in the Indictment, an agreement existed between two or more persons to impair, obstruct, or defeat the ability of the FDA to perform its lawful functions.

Second: That defendants knowingly and willfully joined in that agreement with the purpose of seeing it succeed in accomplishing its unlawful goals.

Third: That one of the conspirators committed an overt act, that is, took an affirmative step in an effort to further the unlawful purpose of the conspiracy, at some time during its existence.

An act is done “knowingly” if a defendant is aware of what he is doing. An act or a failure to act is “willful” if it is done voluntarily and purposefully, with the specific intent to do something the law forbids, that is, with a bad purpose, either to disobey or disregard the law, and not because of accident, ignorance, good faith mistake, or some other innocent reason.

With respect to the conspiracy to defraud the FDA alleged in Count 3, the Indictment alleges, and the government must prove, that for the purpose of deflecting the FDA from carrying out regulatory functions it otherwise would have exercised over NECC, the Count 3 defendants intentionally conspired to deceive the FDA concerning the nature of NECC’s business by making false or misleading statements, or materially misleading omissions despite a duty to disclose the omitted information.

To prove a conspiracy, the government is not required to show that the conspirators entered into an express or formal agreement, or that they directly, by spoken or written words, stated among themselves just what their illegal purpose was, or outlined the details of their scheme, or the means by which they hoped to succeed. Indeed, it would be unusual if there was a formal meeting, or a written contract, or even a specific oral agreement. A conspiracy, by its very nature, is a clandestine enterprise. But the government must prove beyond a reasonable doubt that the Count 3 defendants shared a general understanding of the goals of the conspiratorial agreement. It is not necessary, in order to convict a defendant of a charge of conspiracy, that the objectives or purpose of the conspiracy, whatever they may be, have been achieved or accomplished. The ultimate success or failure of the conspiracy is irrelevant. Rather, the agreement is the essential aspect of the crime of conspiracy.

A person who has no knowledge of or intent to join a conspiracy, but simply acts in a way that furthers some object or purpose of the conspiracy, does not thereby become a conspirator. A

defendant cannot be convicted on the basis of suspicion or surmise; he cannot be convicted because he associated with the wrong people or simply because he knew that they were engaged in illegal activity; nor can he be convicted because he happened to be present while a crime was being committed by others, even if his actions may appear to have furthered the object of the conspiracy. Rather, the government must prove beyond a reasonable doubt that a defendant willfully joined the conspiracy and embraced its illegal purpose.

Proof that a defendant joined in the agreement must be based on evidence of his own words and actions. You need not find that the defendant knew every detail of the conspiracy, or knew every other co-conspirator, or participated in every conspiratorial act alleged by the government, but the government must prove beyond a reasonable doubt that he was aware of the essential terms

of the agreement at issue and intentionally joined the agreement. Even if the defendant was not part of an agreement from its inception, he can be found guilty if at some time during the existence of the conspiracy he knowingly and intentionally became a party to the agreement. A conspirator cannot be held accountable for the crimes of others that are outside the scope of the agreement to which he is a party or crimes committed by others that he could not have reasonably foreseen. Nor can he be held liable for crimes committed by a co-conspirator prior to his joining the conspiracy, even if he is aware that such crimes took place. But once he joins, and so long as he remains a member of the partnership in crime, he is responsible for the words and actions undertaken by his coconspirators that are intended to further the conspiracy's illegal goals.

Accordingly, the reasonably foreseeable acts, declarations, statements and omissions of any member of the conspiracy that are in furtherance of the illegal common purpose of the conspiracy, are deemed, under the law, to be the acts of all of the members, and all of the members are responsible for such acts, declarations, statements and omissions. This is so even if such acts were done and statements were made in the defendant's absence and without his knowledge.

Due Process and Legal Impossibility

The government bears the burden to prove beyond a reasonable doubt that the goals of the alleged conspiracy were unlawful. The Count 3 defendants contend that there was no law clearly distinguishing between a compounding pharmacy and a manufacturer throughout the relevant time period and that the FDA's regulatory authority over compounding pharmacies was unsettled and unclear. Because of the lack of clear law in this area, the Count 3 defendants could not have known whether NECC was a compounding pharmacy or a manufacturer and could not have

intended to impair regulatory functions that the FDA itself was uncertain it possessed. Under these circumstances, the Count 3 defendants assert that the government cannot prove that the alleged conspiracy had an unlawful goal.

When a defendant's objective is to do something that is not a crime, there is a defense of legal impossibility.²⁰ Conspirators cannot be held accountable for conspiring to do something that is not illegal. For example, a hunter cannot be convicted of attempting to shoot a deer if the law does not prohibit shooting deer in the first place.²¹ To meet its burden of proof on Count 3, the government must prove beyond a reasonable doubt that each of the Defendants charged in that count intended to join an agreement whose goal was, in fact, unlawful.

Target of Conspiracy Must be FDA

In Count 3, the government bears the burden to prove beyond a reasonable doubt that the target of the alleged conspiracy was the FDA, as opposed to anyone else.²² The Count 3 defendants contend that no misrepresentations were made to the FDA. They also contend that no representations were made to anyone else for the purpose of defrauding the FDA. The Count 3 defendants further contend that no one else provided any alleged misrepresentations from NECC

²⁰ *In re Doe*, 855 A.2d 1100, 1106 (D.C. Cir. 2004) (When a defendant's objective "is to do something that is not a crime," there is a defense of legal impossibility); *German v. U.S.*, 525 A.2d 596, 606–07 (D.C. Cir. 1987) ("Legal impossibility occurs when a defendant's actions, or actions a defendant causes, even if fully carried out, would not constitute a crime."); *United States v. Dotson*, 407 F.3d 387, 391 (5th Cir. 2005) (legal impossibility exists "when actions which the defendant performs or sets in motion, even if fully carried out as he desires, would not constitute a crime.").

²¹ *United States v. Fernandez*, 722 F.3d 1, 31 (1st Cir. 2013) ("For example, a hunter cannot be convicted of attempting to shoot a deer if the law does not prohibit shooting deer in the first place." (*quoting United States v. Hsu*, 155 F.3d 189, 199 n.16 (3d Cir. 1998))).

²² *Tanner v. United States*, 483 U.S. 107, 130 (1987) ("The conspiracies criminalized by § 371 are defined not only by the nature of the injury intended by the conspiracy, and the method used to effectuate the conspiracy, but also -- and most importantly -- by the *target* of the conspiracy.").

to the FDA.²³ Additionally, the Count 3 defendants maintain that they cannot be found to have conspired to defraud the FDA because the FDA was aware of, and did not object to, the nature of NECC's operations.

Intent and Good Faith

Since an essential element of the crime of conspiracy is the intent to commit the underlying crime, it follows that good faith on the part of a defendant is a complete defense. If you find that the Count 3 defendants believed in good faith that their actions were not criminal, even if they were mistaken in that belief, there would be no crime. As with other material aspects of an offense, the Count 3 defendants have no burden to establish their good faith. The burden is on the government to prove the lack of good faith beyond a reasonable doubt.

²³ *Tanner v. United States*, 483 U.S. 107, 132 (1987) (remanding case with instruction that the defendants' convictions could only stand if: "the evidence presented at trial was sufficient to establish that petitioners conspired to cause [the private company] to make misrepresentations to the [federal agency]" (emphasis added)).

DEFENDANTS' REQUESTED JURY INSTRUCTION 26

COUNTS 32–35, 37, 39–43, and 47–56: Mail Fraud

As I described earlier, the racketeering predicate acts of mail fraud with which Mr. Svirskiy, Mr. Leary, and Mr. Evanosky are each charged are also charged as direct, individual mail fraud counts in the Indictment. Racketeering Acts 54, 64, and 69–78, set out against Mr. Svirskiy in Count 1, are charged as individual mail fraud Counts 32, 42, and 47–56 of the Indictment. Similarly, Racketeering Acts 55, 61–63, 65, and 68, set out against Mr. Leary in Count 1, are charged as individual mail fraud Counts 33, 39–41, 43, and 46 of the Indictment. Racketeering Acts 56–57, 59, and 63, set out against Mr. Evanosky in Count 1, are charged as individual mail fraud Counts 34–35, 37, and 41 of the Indictment. The elements of a mail fraud violation are the same whether it is charged as a RICO predicate act or as a separate count.

As I described before, the Indictment alleges that beginning in at least 2006 and continuing until in or around October 2012, these defendants and others devised a scheme to defraud NECC's customers, and to obtain money and property by means of materially false and fraudulent representations regarding the quality and production of NECC's drugs. Specifically, the Indictment alleges that Mr. Svirskiy, Mr. Leary, Mr. Evanosky, and others at NECC failed to properly test NECC's drugs for sterility; failed to wait for test results before shipping NECC's drugs to customers; failed to inform customers about non-sterile and out-of-specification test results of drugs that had been shipped for use in patients; used expired and expiring ingredients in manufacturing NECC's drugs; used expired and expiring stock solutions in manufacturing the drugs; mixed and mislabeled drug lots to conceal the use of expiring older lots or untested newer lots; employed an unlicensed pharmacy technician to manufacture drugs; failed to properly clean and disinfect the

clean rooms in which drugs were manufactured; and routinely ignored NECC's internal environmental monitoring reports alerting them to mold and bacteria within the clean rooms.

The crime of mail fraud is codified as 18 United States Code, Section 1341. The statute prohibits the use of the mails or an interstate carrier, public or private, in furtherance of any scheme or artifice to defraud, or for obtaining money or property by means of false or fraudulent pretenses, representations, or promises. **As I explained before**, for you to find Mr. Svirskiy, Mr. Leary, or Mr. Evanosky guilty of mail fraud, you must be convinced that the government has proven each of the following four things beyond a reasonable doubt:

First: That there was a scheme, substantially as charged in the Indictment, to defraud or to obtain money or property from NECC's customers by means of false or fraudulent pretenses;

Second: That the scheme involved the misrepresentation or concealment of a material fact or matter, or involved a false statement, assertion, half-truth or knowing concealment concerning a material fact or matter;

Third: That Mr. Svirskiy, Mr. Leary, or Mr. Evanosky knowingly and willfully participated in the scheme with the intent to defraud; and,

Fourth: That for the purpose of executing the scheme or in furtherance of the scheme, Mr. Svirskiy, Mr. Leary, and Mr. Evanosky caused a private or commercial interstate carrier, such as Federal Express, to be used on or about the date alleged.

A scheme to defraud is ordinarily accompanied by a desire or purpose to bring about some gain or benefit to oneself or some other person or by a desire or purpose to cause some loss to another. The term "defraud" means to deprive another of something of value by means of deception or cheating.

The term “false or fraudulent pretenses” means any false statement or assertion that concerns a material aspect of the matter in question, that was either known to be untrue when made or made with reckless indifference to its truth and made with the intent to defraud. The definition includes actual, direct false statements, as well as half-truths and the knowing concealment of facts. To satisfy its burden of proof that a fact is “material,” the government is not required to show that it succeeded in influencing or deceiving the decision maker to whom it was addressed. Rather, a fact or matter is “material” if it has a natural tendency to influence or is capable of influencing the decision maker involved.

A defendant acts “knowingly” if he is aware of his actions, realizes what he is doing, and does not act out of ignorance, mistake, or accident. Intent or knowledge cannot usually be proved by direct evidence because there is no way to directly scrutinize the workings of the human mind. In determining what Mr. Svirskiy, Mr. Leary, or Mr. Evanosky knew or intended at a particular time, you may consider any statements he made or acts that he did or failed to do in the context of all the other facts and circumstances in evidence.

“Intentionally” means purposefully. “Willfully” means to participate voluntarily with the specific intent to do something that the law forbids. To act with “intent to defraud” means to act willfully and with the specific intent to deceive or cheat for the purpose of either causing some financial loss to another or to bring about some financial gain to oneself. As with conspiracy, if Mr. Svirskiy, Mr. Leary, and Mr. Evanosky acted in good faith, they cannot be guilty of the crime of mail fraud.

The law regarding mail fraud is written to punish only those who act knowingly and willfully—that is, purposefully to violate the law, and with the specific intent to defraud. The burden of proving fraudulent intent, as with all other elements of a crime, rests with the government. If you find that

that a defendant was not a knowing participant in the scheme or that he lacked the specific intent to defraud, you should find him not guilty.²⁴

It is not necessary for the government to prove that all of the details alleged in the Indictment concerning the scheme or the material transmitted by mail was false or fraudulent or that the use of the mails was intended as the specific or exclusive means of accomplishing the alleged fraud. What must be proven beyond a reasonable doubt is that a defendant knowingly devised or intended to devise a scheme to defraud that was substantially the same as the one alleged in the Indictment, and that the use of the mails, on or about the dates alleged, was closely related to the scheme because a defendant either received something in the mail or caused it to be mailed in an attempt to carry out the scheme. To “cause the mail to be used” is to do an act with knowledge that the use of the mails, including private commercial carriers, will foreseeably follow in the ordinary course of business.

²⁴ 2 *Modern Federal Jury Instructions (Criminal)*, Instruction 44.01.

DEFENDANTS' REQUESTED JURY INSTRUCTION 27

COUNTS 85–88, 91–92, 94, 96–98, 101–109: Food, Drug and Cosmetic Act Violations

Nature of the Offense

The Indictment alleges three types of violations of the federal Food, Drug and Cosmetic Act, or FDCA. Counts 85–88 charge Mr. Svirskiy, Mr. Leary, and Mr. Evanosky with introducing into interstate commerce adulterated drugs, that is, drugs that were prepared, packed, or stored under unsanitary conditions such that the defendants had a reasonable expectation they could become contaminated. Counts 91–92 and 94 charge Mr. Svirskiy and Mr. Leary with introducing into interstate commerce misbranded drugs, that is, drugs bearing false and misleading labeling. Finally, Counts 96–98 and 101–109 charge Ms. Stepanets, Ms. Chin, and Ms. Thomas with introducing into interstate commerce misbranded drugs, that is, drugs that were dispensed to an end-user patient without a valid prescription by a practitioner licensed by law to administer the drugs. All of these counts were allegedly undertaken with the intent to defraud and mislead.

DEFENDANTS' REQUESTED JURY INSTRUCTION 28

COUNTS 85–88: FDCA – Adulterated Drugs/Insanitary Conditions

In order for you to find Mr. Svirskiy, Mr. Leary, or Mr. Evanosky guilty of introducing adulterated drugs into interstate commerce, you must find that the government proved beyond a reasonable doubt each of the following three elements:

- (1) That Mr. Svirskiy, Mr. Leary, or Mr. Evanosky introduced drugs, or delivered them for introduction into interstate commerce;
- (2) That Mr. Svirskiy, Mr. Leary, or Mr. Evanosky knew that the drugs were adulterated, in that he prepared, packed, or held them under insanitary conditions such that the defendants had a reasonable expectation they could become contaminated; and
- (3) That Mr. Svirskiy, Mr. Leary, or Mr. Evanosky placed the drugs in interstate commerce with the intent to defraud or mislead.

The FDCA defines a “drug” as an “article intended for use in the diagnosis, cure, mitigation, treatment prevention of disease in man,” or, as we would say today, “humans,” “or other animals,” and “articles (other than food) intended to affect the structure or any function of the body of man or other animals.” “Interstate commerce,” as I previously explained, means commerce between any state and any other state.

The term “unsanitary conditions” means conditions in which drugs may become contaminated with filth. “Filth” is used in its ordinary sense of meaning dirty, grimy, or unclean. The government is not required to prove any actual contamination of the drugs to establish adulteration, but only that there was a reasonable expectation that the drugs could become contaminated.

If you find that the government has met its burden of proving the first two elements beyond a reasonable doubt, then you must proceed to the next step, and that is to determine whether Mr. Svirskiy, Mr. Leary, or Mr. Evanosky acted with the intent to defraud and mislead customers. An intent to defraud or mislead signifies a departure from fundamental honesty, or fair play and candid dealings in the general life of the community. To act with an “intent to defraud” means to act knowingly and with the intention or the purpose to deceive or to cheat. An intent to defraud or mislead may be shown by evidence that Mr. Svirskiy, Mr. Leary, or Mr. Evanosky took actions to conceal or prevent the discovery of the truth. The deceit must be about something material, that is, something important that has a natural tendency to influence, or that is capable of influencing, a customer. The government does not have to prove that any customer was in fact influenced, only that Mr. Svirskiy, Mr. Leary, or Mr. Evanosky intended such a result.

As I have previously explained, with any other offense alleging an intent to defraud or mislead, the government must prove beyond a reasonable doubt that Mr. Svirskiy, Mr. Leary, and Mr. Evanosky did not act in good faith.

DEFENDANTS' REQUESTED JURY INSTRUCTION 29

COUNTS 91–92, 94: FDCA – Misbranding/False and Misleading Labeling

Count 91 charges Mr. Svirskiy with introducing misbranded drugs into interstate commerce with the intent to defraud or mislead. Counts 92 and 94 charge Mr. Leary with the same offense. In order for you to find Mr. Svirskiy or Mr. Leary guilty of this offense, again, you must find that the government proved beyond a reasonable doubt:

- (1) Mr. Svirskiy or Mr. Leary introduced drugs, or delivered them for introduction, into interstate commerce;
- (2) That the drugs were misbranded, in that the labeling for the drugs was false or misleading;
- (3) That Mr. Svirskiy or Mr. Leary acted with the intent to defraud or mislead.

A drug is misbranded if any word, statement, or other information required by the FDCA to appear on the label or labeling is false or misleading. “Labeling” means any and all written, printed, or graphic material that accompanies the drug. The labeling need not be false or misleading in its entirety; any single material misrepresentation or material omission in the labeling can make it false or misleading.

A statement is “false” if it was untrue when made.²⁵ A statement is misleading if it misstates, conceals, or omits a material fact and has the effect of deceiving the prospective purchaser or user.²⁶ A fact is “material” for this purpose if it has a natural tendency to influence the recipient or is capable of influencing the decision making of the recipient with respect to representations

²⁵ First Circuit Pattern Criminal Jury Instr. 4.18.1001; *see also* 2 L. Sand et al., *Modern Federal Jury Instructions (Crim.)*, Instr. 36-12 (False, Fictitious, or Fraudulent Statement).

²⁶ *See United States v. Hiland*, 909 F.2d 1114, 1129 (8th Cir. 1990).

made in the labeling, or with respect to consequences which may result from use of the article under the conditions of use prescribed in the labeling or under customary or usual conditions of use.

As I have previously explained, as with any other offense alleging an intent to defraud or mislead, the government must prove beyond a reasonable doubt that Mr. Svirskiy and Mr. Leary did not act in good faith.²⁷

²⁷ See 21 U.S.C. § 321(n); *see also* First Circuit Pattern Criminal Jury Instruction 4.18.1343 (Wire Fraud); *Neder v. United States*, 527 U.S. 1, 16 (1999); *United States v. Gaudin*, 515 U.S. 506, 509 (1995) (for general definitions of materiality); *Watkins*, 278 F.3d at 965-69.

DEFENDANTS' REQUESTED JURY INSTRUCTION 30

COUNTS 96–98, 101–109: FDCA – Misbranding/No prescriptions

Counts 96–98, 101–103, and 108 charge Ms. Stepanets with introducing drugs into interstate commerce without a valid prescription. Counts 104–107 charge Ms. Chin with the same offense, and Counts 108 and 109 charge Ms. Thomas with the same offense.

In order for you to find Ms. Stepanets, Ms. Chin, or Ms. Thomas guilty on these counts you must find that the government has proved beyond a reasonable doubt each of the following four elements:

- (1) That these defendants, considering the evidence against each one individually, introduced drugs, or delivered them for introduction into interstate commerce;
- (2) That a valid prescription for the drugs was required;
- (3) That the drugs were dispensed to end-user patients without such a valid prescription issued by a practitioner licensed by law to administer such a drug; and
- (4) That these defendants dispensed the drugs with the intent to defraud or mislead.

I caution you, however, that the law “will not punish somebody who does not have criminal intent, that such intent means the action is done with a bad purpose, either to disobey or to disregard the law, that the act is not culpable if done because of some mistake or accident or otherwise innocent reason, that negligence, bad judgment, neglect, will not support a violation of Section[s][21 U.S.C. §§ 353(b)(1), 331(a), and 333(a)(2)] and that the government must prove that the [introduction of the drugs into interstate commerce without a valid prescription was done

with an ‘intent to defraud or deceive;’ that is, it was] done willfully and intentionally, not by inadvertence or by carelessness.”²⁸

I also instruct you that the law requires you to find Ms. Stepanets, Ms. Thomas, and Ms. Chin *not* guilty of these charges if you find that any introduction of the drugs into interstate commerce was done by the defendants in good faith.

Section 353(b)(1) of the FDCA states that prescription drugs “shall be dispensed only upon a written prescription of a practitioner licensed by law to administer such drug... and the act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded.”

The term “dispensing” means the filling of a medical prescription and the delivery of it to the end-user patient. In other words, a pharmacist dispenses a drug when he acts in his role as a licensed professional authorized to fill, that is put together, a medical prescription and then delivers it to the end-user.

A “prescription” means a written order, that is, directions, or constitutes directions, for the preparation and administration of a medicine, remedy, or drug for a patient²⁹ who needs it after an examination or consultation by a licensed practitioner who has a physician-patient relationship with the patient. To be valid under the FDCA, a prescription must be issued in the usual course of a professional practice for a legitimate medical purpose. Federal law does not

²⁸ See *United States v. Young*, 955 F.2d 99, 105 (1st Cir. 1992) (internal quotation marks omitted), cf. *Green v. United States*, 474 U.S. 925, 88 L. Ed. 2d 266, 106 S. Ct. 259 (1985) (White, J., dissenting).

²⁹ The Court previously modified the term patient as “real” patient. That modifier has been removed. All relevant drugs were ordered by a medical facility for “real” patients. The question of the factual and legal effect of any “fake” names on prescriptions is for the jury.

require a prescription to include the name of the patient in order to be valid.³⁰ Whether a prescription has been issued in the usual course of a professional practice for a legitimate medical purpose under the FDCA is determined in part by reference to the laws and regulations of the state in which the particular physician is licensed to practice medicine.

³⁰ Section 353(b)(1) does not define the term “prescription.” However, 21 U.S.C. § 353(b)(2) provides that prescribed drugs need not fulfill all the labeling requirements of 21 U.S.C. § 352, provided that “the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, *if stated in the prescription, the name of the patient....*” 21 U.S.C. § 353(b)(2) (emphasis added). The inescapable implication of the clause “if stated in the prescription, the name of the patient” is that a prescription need not state a name in order to be valid. It is a fundamental principle of statutory interpretation that the statute must be read as a whole. *See, e.g., O’Connell v. Shalala*, 79 F.3d 170, 176 (1st Cir. 1995) (“a court engaged in the task of statutory interpretation must examine the statute as a whole, giving due weight to design, structure, and purpose as well as to aggregate language.”). To interpret the word “prescription” in § 353(b)(1) as requiring the name of a patient, where in § 353(b)(2) it explicitly does *not*, would defy that principle and result in an unjust and incoherent reading of the statute.